DEPARTMENT OF HEALTH & HUMAN SERVICES
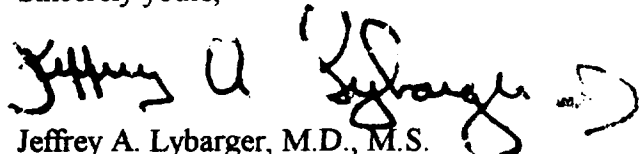
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Public Health Service

Agency for Toxic Substances
and Disease Registry
Atlanta GA 30333

June 21, 2001

Dear Colleague:

Enclosed are the notes from the data analysis workshop that we conducted May 15 and 16 in Denver, Colorado. These notes only include the data analysis portion of the discussion. Suggestions for additional analyses or research will be provided in a later communication. Please review the notes to identify any errors or omissions. ATSDR will be proceeding with the data analysis and we will revise the analysis based upon suggested changes. Thank you for your help. We will be providing information to you regarding the analysis soon.

Sincerely yours,

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Notes of the Data Analysis Planning Meeting Regarding the Analysis of Medical
Testing Conducted for Asbestos Related Abnormalities Among Persons Exposed to
Contaminated Vermiculite in Libby, Montana

The purpose of this meeting was to consider possible data analyses for medical testing data
conducted in Libby, Montana for persons exposed to contaminated vermiculite. A large number
of analyses are possible. The team recommended that a general report with a good extent of
descriptive data be completed this summer for community distribution. This report should not
wait for analyses that may be more sophisticated or research oriented that might take more time
to complete. For that reason, these notes are divided into two sections. Section 1 provides
recommendations for the community report. Section 2 summarizes ideas for additional analyses.

Section 1. The community report

Concerns that have been heard from the community for which the analysis should consider
including information.

Prevalence rates of illness and symptoms
Abnormality rates by age - this especially concerns young adults as a way of gaining some
incite on children.
Some evaluation of people with vermiculite insulation.
The analyses conducted for the interim report which summarized abnormality rates by
exposure group were well received. These include analyses by
Age
Sex
Residential History
Occupational History (including military)
Household contact
Recreations
Smoking History

Abnormality Outcomes
Any Reviewer: Interstitial changes PA view
and ≥2 b-readers   Plural changes PA view
                     Plural changes Oblique views
                     Plural changes All views

                     PFT FEV1, FVC, FEV1/FVC ratio

Exposure characterization
      Evaluate ways to integrate multiple exposures from several known exposure routes
          (such as a person who has all of recreational, household and worker
          contact)
      Length of exposures by group

Residential exposure	- time since first exposure
	- total exposure
Occupational	- total time of doing activity if available from questionnaire.
	- time since first exposure
Recreational	- time since first exposed
	(It was felt that misclassification of trying to estimate total exposures via this pathway was likely great without an extensive and sophisticated modeling attempt.)
Household	- time since first exposed
	- total time of exposure

Exposure Factors to Qualitatively Review
      Other Occupation with contact to exposure
      Military Asbestos contact or onboard ship

Review line listing of exposure potential for all persons with insulation only or no know exposure.

Multi variate Model Factors
      If Multi variate models are used, factors to consider are:
          Age
          Sex
          Age of first exposure
          Years since first exposure
          Duration of exposure
          Body Mass Index (some considered dichotomizing the data at a level of 0.3
              for Morbid Obesity.
          Smoking (never, ex-, current, pack-years)

Characterizing Abnormalities by Severity

Interstitial Disease - by ILO grade into major grades of 0, 1,2, and 3.

Plural Disease -   1.- no abnormalities
                      2.- mild; lesion restricted to the costophrenic angel by 2 b-readers
                              (3.A + 3.B.b only)
                      3. - moderate; plural chest wall or diaphramatic circumscribed
                              lesions but no diffuse lesions seen
                              (3.A + 3.B.a &/or 3.C.a. AND 3.C.b is Neg.)
                              Unilateral or bilateral - if any b-reader considers it bilateral
                              then consider it as bilateral
                      4.- extensive; diffuse plural lesions
                              (3.A + 3.C.b)
                              Unilateral or bilateral - if any b-reader considers it bilateral
                              then consider it as bilateral

PFT Function -   FVC   mild   ≤% of predicted
                               moderate   ≤% of predicted
                               severe   ≤% of predicted

                  FEV1   mild   ≤% of predicted
                               moderate   ≤% of predicted
                               severe   ≤% of predicted

                  FVC/FEV1   mild   ≤% of predicted
                               moderate   ≤% of predicted
                               severe   ≤% of predicted

Association between severity of interstitial radiologic changes and pulmonary function changes and each with symptoms

    Interstitial changes by major category vs. FVC, FEV1 and FEV1/FVC
    Plural changes by presence or absence vs. FVC, FEV1 and FEV1/FVC
            (PFT severity grades of mild, medium, severe)
            (If 2 b-reads, use the lowest major category; If 3 b-reads take the medium)
            (Use all PFTs with acceptable or sub-optimal quality; do not use unacceptable)
    Symptoms
            Shortness of Breath (questions 66 a,b,c,or d)
            Cough - chronic (question 59)
            Cough - dry (question 65)
            Cough - any (questions 65 + 59)
            Pleuritic Chest Pain.- (question 62)

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Adjustment factors for Multi variate evaluation of associations:
   smoking
   BMI
   recommended using raw PFT values in cubic cm.; therefore, adjustment will need
   to include age, sex, ht, and race (expected 15% less for African people)